

NIH-FDA Tobacco Control Regulatory Science

NIH Revision Applications for Research Relevant to the Family Smoking Prevention and Tobacco Control Act (P30)

Pre-Application Webinar for RFA-OD-12-007 (P30)

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Participating: NCI, NHLBI, NIAAA,, NIDA, NIMH, FDA-CTP



Research Objectives and Scope

- Science will inform the FDA in regulation of the manufacture, marketing, and distribution of tobacco products
- By way of background, FDA CTP developed a list of 56 research priorities



This FOA: ten CTP interest areas

- Only applications proposing research projects/pilots relevant to one or more of these ten areas will be considered for funding
- Speak to program official from the organization funding the parent center (NCI, NHLBI, NIAAA,, NIDA, NIMH) regarding responsiveness



Research Projects

- All applicants must propose one to four research projects that respond to one or more of the ten areas of research interest
- The projects may be self-standing or mutually thematically related.
- At the applicant's discretion, the scope of the proposed projects may be similar to typical R01 projects and/or pilot or small projects (R21 and R03).



Letter of Intent

- Number and title of this funding opportunity
- Parent grant number (& PI)
- Names of other key personnel
- Descriptive title of proposed research
- Specific aims



NIH Revision Applications (p30)

- Expand the scientific foundation for regulatory and policy issues relevant to the work of the FDA Center for Tobacco Products
- Build research capacity and scientific expertise



Critical: Ensuring your research is within scope

- Examples of research topics *not* within scope
 - Development or evaluation of cessation treatments
 - Identification of targets for drug development
 - Examination of regulations or policies not under FDA's purview, e.g., clean indoor air laws
- Gray areas: Confirm!
 - Cessation
 - Disease processes, associations, mechanisms



Critical: Ensuring your research is within scope

- All research must fall within the regulatory authority of the FDA CTP
- Strongly Recommended:
 - Familiarize yourself with FDA CTP's regulatory authorities:
<http://www.fda.gov/TobaccoProducts/default.htm>
 - Explain how the findings from your proposed research will inform FDA's regulatory authority over the manufacture, marketing, and distribution of tobacco products
 - in your letter of intent
 - within your application
 - Discuss your research with the Scientific/Research Contact from the Institute relevant to your research
 - FAQs -
<http://prevention.nih.gov/tobacco/docs/FAQs%20for%20P30.pdf>



Scientific Research Contacts

- NCI: Glen Morgan, PhD, gmorgan@nih.gov
- NHLBI: Antonello Punturieri, MD, PhD, punturiera@nhlbi.nih.gov
- NIAAA: Abraham Bautista, PhD, bautista@mail.nih.gov
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